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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,670	07/21/2003	Yuanhao Li	CELL-024	1674
29585 7590 03/13/2007 DLA PIPER US LLP 153 TOWNSEND STREET SUITE 800 SAN FRANCISCO, CA 94107-1957			EXAMINER CHEN, SHIN LIN	
			ART UNIT 1632	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/624,670

Applicant(s)

LI ET AL.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-21 is/are pending in the application.
4a) Of the above claim(s) 1-6 and 10 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 9 and 11-21 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed on 12-22-06 has been entered. Claims 9 and 16 have been amended. Claims 1-6 and 9-21 are pending. Claims 9 and 11-21 are considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 9 and 11-21 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention and is repeated for the reasons set forth in the preceding Official action mailed 9-26-06. Applicant's arguments filed 12-22-06 have been fully considered but they are not persuasive.

Applicants cite GenBank Accession No. on page 3, paragraph 12 for the basis of "prenylated protein tyrosine phosphatase" (amendment, p. 5). This is not found persuasive because the GenBank Accession No. cited in paragraph 12 is AC100803.1, however, a search for this accession number shows that it has been replaced with 100803.2, and it is a sequence of Homo sapiens chromosome 8, clone CTB-3064M3. There is no mention of "prenylated protein tyrosine phosphatase". Therefore, there is no support for the phrase "prenylated protein tyrosine phosphatase" in the specification.

Applicants cite paragraph 102 of the specification for the basis of the phrase "wherein said sequence is obtained from ...and has the transcriptional regulatory factor activity of the PRL-3 TRE sequence" (amendment, p. 5). This is not found persuasive because paragraph 102

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of the specification fails to mention the phrase set forth above. Thus, the claims remain rejected for the reasons or record.

3. Claim 9 recites the limitation "said sequence" in line 4. There is insufficient antecedent basis for this limitation in the claim. Applicants' amendment filed 12-22-06 necessitates this new ground of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9 and 11-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' amendment filed 12-22-06 necessitates this new ground of rejection.

The phrase "prenylated protein tyrosine phosphatase 3 gene" in the amended claim 9 is considered new matter. Applicants cite GenBank Accession No. on page 3, paragraph 12 for the basis of "prenylated protein tyrosine phosphatase" (amendment, p. 5). The GenBank Accession No. cited in paragraph 12 is AC100803.1, however, a search for this accession number shows that it has been replaced with 100803.2, and it is a sequence of Homo sapiens chromosome 8,

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clone CTB-3064M3. There is no mention of “prenylated protein tyrosine phosphatase”.

Therefore, there is no support for the phrase “prenylated protein tyrosine phosphatase” in the specification. Thus, the phrase “prenylated protein tyrosine phosphatase 3 gene” in the amended claim 9 is considered new matter. Claims 11-21 depend from claim 9.

The phrase “wherein said sequence is obtained from ...and has the transcriptional regulatory factor activity of the PRL-3 TRE sequence” in claim 9 is considered new matter. Applicants cite paragraph 102 of the specification for the basis of the phrase “wherein said sequence is obtained from ...and has the transcriptional regulatory factor activity of the PRL-3 TRE sequence”. However, paragraph 102 of the specification fails to mention the phrase set forth above. There is no support in the specification for the recited phrase set forth above. Thus, the phrase “wherein said sequence is obtained from ...and has the transcriptional regulatory factor activity of the PRL-3 TRE sequence” in claim 9 is considered new matter. Claims 11-21 depend from claim 9.

6. Claims 9 and 11-21 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a PRL-3 TRE sequence comprising the sequence of SEQ ID No. 1, does not reasonably provide enablement for the use of various PRL-3 TRE sequence derived from the sequence of SEQ ID No. 1 and a composition comprising the replication-competent adenovirus vector as claimed for pharmaceutical use. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims and is repeated for the

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reasons set forth in the preceding Official action mailed 9-26-06. Applicant's arguments filed 12-22-06 have been fully considered but they are not persuasive.

Applicants amended claim 9 to recite the PRL-3 TRE sequence is obtained from the 0.6kb sequence upstream of the translational start codon for the PRL-3 gene (amendment, p. 6). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 9-26-06. Since it is the sequence "obtained" from the 0.6kb upstream sequence, the sequence encompasses any fragment or subsequence of the 0.6kb sequence. The structural feature that contributes to the TRE activity has not been disclosed. The specification only discloses the nucleotide sequences of SEQ ID No. 1 and 2, but there is no structure-function analysis of the disclosed TREs to provide guidance on the essential nucleotides or structure of the molecule that could be modified and still retains function. There is no teachings in the prior art regarding the elements that are responsible for the specific activity of a TRE that would provide guidance on which fragments of the polynucleotide shown in SEQ ID No. 1 or what kind of modification would still retain activity. Absent specific guidance, one skilled in the art at the time of the invention would not know what kind of activity would be for those various TREs obtained from SEQ ID No. 1, and would not know how to use those TREs obtained from SEQ ID No. 1. Thus, one skilled in the art at the time of the invention would require undue experimentation to practice over the full scope of the invention claimed.

Conclusion

No claim is allowed.

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7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

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(866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.



SHIN-LIN CHEN
PRIMARY EXAMINER